

In determining whether termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process, the agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for the debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that, despite the seriousness of the offense for which Dr. Chatterji was debarred, his conduct may have been an aberration, his character and scientific ability remain highly regarded by his professional peers, and that he may serve as a strong advocate for compliance with current good manufacturing practice regulations. For these reasons, the agency finds that termination of Dr. Chatterji's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Chatterji's period of debarment has lasted more than 1 year.

Accordingly, the Deputy Commissioner for Operations, under section 306(d)(4) of the act and under authority delegated to him (21 CFR 5.20), finds that Dr. Dulal C. Chatterji's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Deputy Commissioner for Operations further finds that because the agency is granting Dr. Chatterji's application, an informal hearing under section 306(d)(4)(C) of the act is unnecessary.

As a result of the foregoing findings, Dr. Dulal C. Chatterji's debarment is terminated effective June 11, 1998 (section 306(d)(4)(C) and (d)(4)(D) of the act).

Dated: June 5, 1998.

Michael A. Friedman,

Acting Commissioner of Food and Drugs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 29 and 30, 1998, 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 29, 1998, the committee will discuss, make recommendations, and vote on a premarket approval application for an external compression device used in cardiopulmonary resuscitation. On June 30, 1998, the committee will discuss and make recommendations on permanent cardiovascular implants such as heart valves and vascular grafts.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 18, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on June 29 and 30, 1998. Near the end of committee deliberations on both days, a 30-minute open public session will be conducted to address issues specific to the submission or topic before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral

presentations should notify the contact person before June 18, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 4, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0489]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "(Petition for) Administrative Reconsideration of Action" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 26, 1998 (63 FR 14717), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0192. The approval expires on May 31, 2001.

Dated: June 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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